K024214

SECTION 9

MAR 12 2003

510(k) SUMMARY

This 510(k) summary of safety and effectiveness for KaVo Everest Titanblank is submitted in accordance with the requirements of SMDA 1990 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant: KaVo America

Address: 340 East Main Street
Lake Zurich, IL 60045

Manufacturer: CHEMICHL, AG
Landstrasse 114
P.O. 732
VADUZ, LIECHTENSTEIN
GERMANY FL 9490

Contact Person: Ms. Jennifer Pottala

Telephone: 847-550-6800
847-550-6825 (Fax)
800-323-8029

Preparation Date: December 2002
(of the Summary)

Device Name: KaVo Everest Titanblank

Common Name: Titanium metal for use in dentistry

Classification: There is no classification regulation for titanium.
Base metal alloy: 21 CFR 872.3710
Base metal alloy: Class II
Product Code: EJH
Panel: 76

Predicate devices: DC Titan

Device description: KaVo Everest Titanblank consists of pure (99.5+%) titanium blanks..

Indications: KaVo Everest Titanblank is indicated for use in the preparation or manufacture of permanent or removable dental appliances.

KaVo proposes that the KaVo Everest Titanblank distributed in the United States be labeled:

"CAUTION: Federal (US) law restricts the use of this device to sale to or on the order of licensed professionals."

Performance Data: None required. The claim of substantial equivalence is based on purity of the titanium (99.5+%).

CONCLUSION: Based on the information in the notification KaVo America believes that the KaVo Everest Titanblank is substantially equivalent to the claimed predicate, DC Titan.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 12 2003

Ms. Jennifer Pottala
New Product Manager
KaVo America Corporation
340 East Main Street
Lake Zurich, Illinois 60047

Re: K024214
Trade/Device Name: KaVo Everest Titanblank
Regulation Number: 872.3710
Regulation Name: Base Metal Alloy
Regulatory Class: II
Product Code: EJH
Dated: December 20, 2002
Received: December 20, 2002

Dear Ms. Pottala:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 7

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K024214

Device Name: KaVo Everest Titanblank

Indications for Use Statement:

KaVo Everest Titanblank is indicated for use in the preparation or manufacture of permanent or removable dental appliances.

KaVo proposes that the materials, when intended for distribution in the United States, be labeled:

CAUTION: Federal (US) law restricts the sale of this device to, or on the order of, licensed professionals.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use X OR Over-The Counter Use ___
(Per 21 CFR 801.109)

Ken Mulley for MSD
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K024214